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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/753,061

01/08/2004

Johan Boelens

17601.43

2469

57360

7590

04/10/2009

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EXAMINER

MCDOWELL, SUZANNE E

ART UNIT

PAPER NUMBER

1791

MAIL DATE

DELIVERY MODE

04/10/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/753,061	Applicant(s) BOELENS ET AL.	
	Examiner Suzanne E. McDowell	Art Unit 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102/103

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

3. (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4 and 9 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Johnson et al. (EP 1,132,059). Johnson et al. teaches the basic method claimed as follows: folding a balloon into a number of longitudinal pleats, either manually or by machine [0031], placing the balloon into a mold, and pressurizing and heating the mold [0035]-[0036] to result in a balloon with spaced apart protrusion (see Fig. 2, element 44), where the balloon may be held with or without a stent [0039], or may be held by a PTFE spiral cut phantom stent [0040]-[0041]. It is the position of the examiner that the spiral cut phantom stent, which is removed from the balloon after processing, is a “member wrapped” around the balloon, with the member having spaced-apart loops, i.e., spirals. In the alternative, forming a stent with the spiral cuts being spaced apart is notoriously well known in the art. It would have been obvious to a person of ordinary skill in the art to use a well known apparatus, such as a stent with the spiral cuts

Art Unit: 1791

being spaced apart, to modify the method taught by Johnson et al., in order to form a balloon with the desired finished appearance.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 5-8 and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (EP 1,132,059) in view of Blackshear, Jr. et al. (US Patent 5,308,356). Johnson et al. teaches the basic method claimed as follows: folding a balloon into a number of longitudinal pleats, either manually or by machine [0031], placing the balloon into a mold, and pressurizing and heating the mold [0035]-[0036] to result in a balloon with the desired configuration where the balloon may be held with or without a stent [0039], or may be held by a PTFE spiral cut phantom stent [0040]-[0041]. Regarding claims 5, 11 and 15, Johnson et al. does not teach that the balloon is initially formed by forming a tube in a mold. Blackshear, Jr. et al. teaches a method of making a balloon catheter with protrusion thereon created by a helical wrap, where the balloon is initially formed by inflating a small tube in a heated mold (column 6, lines 41-46). It would have been obvious to a person of ordinary skill in the art to sue the method taught by Blackshear, Jr. et al. to further define the method taught by Johnson et al., in order to quickly and easily form the initial balloon. The

Art Unit: 1791

motivation to use the teachings of Blackshear, Jr. et al. to modify the teachings of Johnson et al. is that both are in the same field of endeavor, that of forming balloons.

Regarding claims 6, 12 and 16. Johnson et al. teaches using the balloon with a catheter system.

Regarding claims 7 and 13, Johnson et al. does not teach that the folding and the application and removal of the member are accomplished manually. Regarding claims 8 and 14, Johnson et al. does not teach that the folding and the application and removal of the member are accomplished by machine. It is generally well known in the art to fold balloons utilizing the actual stent, or by hand, or by using a folding machine or balloon wrap device. These methods are known equivalents for forming balloons. It would have been obvious to a person of ordinary skill in the art to choose any well known equivalent, such as by hand or a machine, to wrap the balloon or the forming member around the balloon, depending upon the desired finished appearance of the balloon, including the design of the folds or the wrap member.

7. Claims 10, 17 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Johnson et al. (EP 1,132,059). Johnson et al. teaches the basic method claimed as follows: folding a balloon into a number of longitudinal pleats, either manually or by machine [0031], placing the balloon into a mold, and pressurizing and heating the mold [0035]-[0036] to result in a balloon with spaced apart protrusion (see Fig. 2, element 44), where the balloon may be held with or without a stent [0039], or may be held by a PTFE spiral cut phantom stent [0040]-[0041]. Regarding claim 10, Johnson et al. does not teach that the folding is accomplished by wrapping the member around the balloon. Regarding claim 17, Johnson et al. does not teach that the member is applied and removed manually. Regarding claim 18, Johnson et al. does not teach that the member is applied and removed by a

Art Unit: 1791

machine. It is generally well known in the art to fold balloons utilizing the actual stent, or by hand, or by using a folding machine or balloon wrap device. These methods are known equivalents for forming balloons. It would have been obvious to a person of ordinary skill in the art to choose any well known equivalent, such as by hand or a machine, to wrap the balloon or the forming member around the balloon, depending upon the desired finished appearance of the balloon, including the design of the folds or the wrap member.

Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burnham (US Patent 5,244,619).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suzanne E. McDowell whose telephone number is (571) 272-1205. The examiner can normally be reached on Monday and Wednesday 8:30-4; Tuesday and Thursday 10-2.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Crispino can be reached on (571) 272-1226. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

Art Unit: 1791

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Suzanne E. McDowell/
Primary Examiner, Art Unit 1791

SEM
March 29, 2009